## NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES HUMAN RESEARCH ETHICS PROGRAM

## POST IRB APPLICATION SUBMISSION FLOWCHART: INTRAMURAL AND EXTRAMURAL SUBMISSIONS

STEP 1	STEP 2	STEP 3	STEP 4
UMDNJ IRB	IRB REVIEWERS	PRINCIPAL INVESTIGATOR	UMDNJ IRB
Upon receipt of materials the IRB Program Assistant will:	Responsibilities:	Responsibilities:	Responsibilities:
<ol> <li>Review IRB application materials for completeness. Work directly with the PI for items still required.</li> </ol>	IRB reviewers will assess application materials to ensure the ethical protection of research subjects. They will contact the principal	The principal investigator has ninety (90) days to provide the IRB with a written response to the IRB Debriefing Letter.	Upon approval the IRB Program Assistant will send the principal investigator the IRB Approval Letter with a
2. Assign the application an IRB control number.	investigator directly for clarification, if necessary.	Upon receipt of the principal investigator's response, the IRB Program Assistant will forward it	copy sent to HREP.
3. Assign IRB reviewers based on the level of review required.	Upon completion of their review they will submit their determination to the IRB Program Assistant who will send the principal	to the same IRB reviewers who will approve, disapprove or require additional modifications so that the application can be approved.	
*The IRB will only accept applications submitted from HREP with an HREP certification letter.	investigator an IRB  Debriefing Letter containing questions, concerns, requests for additional information or requirements for modification.	Investigators may contact IRB reviewers to discuss the issues identified in the IRB Debriefing Letter, and request their review of any modifications so as to ensure revisions meet the IRB reviewers' requirements.	
		Investigators may contact HREP for additional assistance or guidance during the IRB review process.	